REMARKS

The Final Office action dated April 27, 2010 is acknowledged. Claims 1, 4-6, 8-11 and 13-36 are pending in the instant application. Claims 15-19, 30-32 and 36 have been withdrawn from consideration. Claims 1, 4-6, 8-11 and 13-36 have all been rejected in the present Final Office action. By the present Final Office Action response, claim 1 has been amended to delete alginates and alginic acid from the group of matrix-forming polymers. Reconsideration is respectfully requested in light of the amendments and arguments made herein. No new matter has been added.

Rejection of claims 1, 4-6, 8-11 and 13-36 under 35 U.S.C. 103(a)

Claims 1, 4-6, 8-11, 13, 14, 21-29 and 33-35 remain rejected as being unpatentable over U.S. Patent No. 4,572,832 (Kigasawa, et al.) in view of U.S. Patent No. 5,900,247 (Rault, et al.) for the reasons set forth in the Office action dated September 30, 2010. In particular, the Examiner states that Kigasawa, et al. disclose soft buccal administration forms of active ingredients that can be formulated as disks or wafers, as discussed above. However, the Examiner states that Kigasawa, et al. fail to disclose a multilayer dosage form.

The Examiner refers to Rault, et al. and states that the reference discloses a bioadhesive pharmaceutical composition to locally release active ingredients through various mucosal membranes, and that the bioadhesive composition comprises a vinyl acetate/polyvinylpyrrolidinone copolymer, at least one active ingredient, optionally a cellulose or cellulose derivative such as ethyl cellulose or hydroxypropylmethyl cellulose and excipients such as plasticizers, flavoring agents or sweeteners. The Examiner further states that after spreading of the bioadhesive mixture onto a biodegradable or non-

biodegradable protective film or substrate, the assembly is dried and the protective film is chosen for its adhesive or bioadhesive properties and is peelable. According to the Examiner, this process results in the production of a multilayered administration form and that in Example 4 of the reference, a composition is prepared which contains approximately 3% by dry weight of flavoring agents.

The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a buccal administration form as taught by Kigasawa, et al. and to place this material on a protective film as taught by Rault, et al., resulting in a multilayered administration form. The Examiner also concludes that Rault, et al. provide additional guidance to one skilled in the art as to the amount of flavoring ingredients, which can include aroma substances, that can be added to such compositions.

Claims 1, 4-6, 8-11, 13, 14, 21-29 and 33-35 remain rejected as being unpatentable over Kigasawa, et al. and Rault, et al. as applied to claims 1, 4-6, 8-11, 13, 14, 21-29 and 33-35 above, and further in view of U.S. Publication No. 2003/0099691 (Lydzinski, et al.) for the reasons set forth in the previous Office action. In particular, the Examiner states that Kigasawa, et al. disclose soft buccal compositions which comprise a medicament to be absorbed through the oral cavity, a water-soluble protein, a polyhydric alcohol and a fatty acid ester and/or a carboxyvinyl polymer, as well as that additives can be added in addition to the require ingredients, including flavorings, such as menthol, lemon oil and citrus flavor, as well as other excipients, disintegrating adjusting agents, emulsifiers, dispersants, binders and thickeners. However, the Examiner states that Kigasawa, et al. fail to disclose a formulation wherein the substance is one or more aroma

substances without a pharmaceutical active substance being included in the administration form.

The Examiner refers to Lydzinski, et al. and states that the reference discloses an oral film that is useful for delivering an agent to an animal or human to produce either a therapeutic or cosmetic effect, such as breath fresheners or fragrances and that the active agent can be used in any amount desired, the only limitation being the potential load of the film, but generally that the amounts used will range from about 0.5% to about 15%, with substantially higher amounts for breath fresheners than for pharmaceutical agents.

The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate an aroma substance in place of the pharmaceutically active ingredient in the compositions of Kigasawa, et al. with the motivation that it would have been reasonable to have expected success since the inclusion of an aroma substance results in an oral film that quickly disintegrates in the mouth, leaving the user with fresh or scented breath. Moreover, the Examiner states that as Lydzinski, et al. teach, almost any amount of active substance can be present in the film and the type of active ingredient will determine how much is added, with pharmaceutically active substances generally present in lower amounts than breath freshener ingredients.

Claims 1, 4, 5, 9-11, 13, 14, 21, 22, 24, 25, 27-29, 33 and 34 remain rejected as being unpatentable over U.S. Patent No. 4,764,378 (Keith, et al.) view of Rault, et al. In particular, the Examiner states that Keith, et al. disclose buccals dosage forms containing up to 10% by weight active ingredient, in a matrix-forming polymer mass but fail to disclose a multi-layer dosage form.

The Examiner refers to Rault, et al. for disclosing a bioadhesive pharmaceutical composition to locally release active ingredients through various mucosal membranes, and that the bioadhesive composition comprises a vinyl acetate/polyvinylpyrrolidinone copolymer, at least one active ingredient, optionally a cellulose or cellulose derivative such as ethyl cellulose or hydroxypropylmethyl cellulose and excipients such as plasticizers, flavoring agents or sweeteners. The Examiner further states that after spreading of the bioadhesive mixture onto a biodegradable or non-biodegradable protective film or substrate, the assembly is dried and the protective film is chosen for its adhesive or bioadhesive properties and is peelable. According to the Examiner, this process results in the production of a multilayered administration form.

The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a buccal administration form as taught by Keith, et al. and to place this material on a protective film as taught by Rault, et al., resulting in a multilayered administration form.

Claims 1, 4, 5, 8-11,13, 14, 21, 22, 24, 25, 27-29, 33 and 34 remain rejected as being unpatentable over Keith, et al. and Rault, et al. as applied to claims 1, 4, 5, 9-11, 13, 14, 21, 22, 24, 25, 27-29, 33 and 34 above, and further in view of WO 99/53897 (Bergeron, et al.) and EP 0386960 (Gibson, et al.). In particular, the Examiner states that Keith, et al. disclose buccals dosage forms containing up to 10% by weight active ingredient, in a matrix-forming polymer mass but fail to disclose the presence of an agent that alters the pH from the Markush group of claim 8.

The Examiner refers to Bergeron, et al. for disclosing a formulation of film-forming ingredient and an active agent for topical formulations and that the pH of the

formulation can be adjusted to meet the requirements of the target tissue. For example, formulations applied to the vaginal mucosa a pH of about 4.0-4.5 should be used. The Examiner points out that Bergeron, et al. fail to disclose any agents that would adjust the pH depending on the target tissue.

The Examiner refers to Gibson, et al. for disclosing that the pH of the compositions can be adjusted through the use of pharmaceutically acceptable acids or bases such as sodium or hydrochloric acid and that pH can be maintained by the use of buffering agents.

The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a pH adjusting agent in the compositions of Keith, et al. in view of the teachings of Bergeron, et al. and Gibson, et al.

Claims 1, 4-6, 9-11, 13, 14, 21-25, 27-29 and 33-35 remain rejected as being unpatentable over Keith, et al. and Rault, et al. as applied to claims 1, 4, 5, 9-11, 13, 14, 21, 22, 24, 25, 27-29, 33 and 34 above, and further in view of Lydzinski, et al. In particular, the Examiner states that Keith, et al. disclose buccals dosage forms containing up to 10% by weight active ingredient, in a matrix-forming polymer mass and that the active ingredients are pharmaceutically active compounds like scopolamine or verapamil hydrochloride. The Examiner states that the reference fails to disclose a formulation wherein the active substance is one or more aroma substances without a pharmaceutical active substance being included in the administration form.

The Examiner refers to Lydzinski, et al. for disclosing an oral film that is useful for delivering an agent to an animal or human to produce either a therapeutic or cosmetic

effect, such as breath fresheners or fragrances, both of which allegedly read on the aroma substance of the instant claims.

The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate an aroma substance in place of the pharmaceutically active ingredient in the compositions of Keith, et al. in view of the teachings of Lydzinski, et al.

It is respectfully submitted that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the teachings of the cited prior art alone or in combination, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants respectfully disagree with the Examiner's position for at least the numerous deficiencies of Kigasawa, et al. and Keith, et al., and the secondary and tertiary references already of record in the previous Office action responses. In particular, neither primary reference of Kigasawa, et al. and Keith, et al. teach or disclose buccal dosage forms for transmucosal administration of a pharmaceutically active substance, wherein the buccal dosage form comprises a matrix forming polymer selected from the group

consisting of pullulan, polyacrylamides, chitosan, arabinogalactan, galactomannan, agar-agar, agarose and carrageenan. Still further, none of the cited secondary or tertiary references make up for any of the numerous deficiencies of Kigasawa, et al. and Keith, et al. Therefore, the combination of teachings of the references fails to teach each and every limitation of the present claims, and thus fail to render the presently claimed invention obvious.

In particular, no combination of teachings of the references would render obvious to one skilled in the art a multi-layered, film-shaped administration form for transmucosal administration of at least one active substance, said administration form being applied to the oral mucosa of a herbivore, to the human oral mucosa, to the human nasal mucosa or to the human vaginal mucosa and wherein said administration form comprises a base mass for producing said administration form, said base mass comprising at least one matrix-forming polymer selected from the group consisting of pullulan, polyacrylamides, chitosan, arabinogalactan, galactomannan, agar-agar, agarose and carrageenan, wherein the base mass has a pH value in the presence of water or of a water-containing solvent mixture, wherein during the production of the administration form, the pH value of the base mass for producing the administration form is approximated or adapted to the physiological pH value of the mucosa to which the administration form is to be applied, the pH being at 8-9 when the mucosa is a herbivoral mucosa, between 5.5-6.5 when the mucosa is a human oral mucosa, at about 6 when the mucosa is a human nasal mucosa or at about 4 when the mucosa is a human vaginal mucosa, and where the at least one active substance is selected from the group consisting of pharmaceutically active substances and aroma substances.

In view of the above, the Applicants respectfully request that the obviousness rejections be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicants strongly urge that the obviousness-type rejection and anticipation rejections be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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